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## CERTIFICATE OF ANALYSIS

MAGNESIUM HYDROXIDE  
HD12 ND  
WHITE PAPER BAG 25

Shipment number: 306164  
P.O. Number: 50000039366

Manufacturing and quality control of Magnesium Hydroxide (API) were performed in accordance with the EU GMP guide, Part II - Basic Requirements for API's (ICH Q7)

Product: Magnesium Hydroxide, HD12 ND grade, current EP

Description: A white, fine, odorless powder, almost insoluble in water and alcohol.

Dissolves in dilute mineral acids.

<u>Inspection Characteristics</u>	<u>Batches&gt;&gt;&gt;</u>	<u>308233060</u>
ASSAY(as Mg(OH)2)	95.0-100.5%	99.9
Identification	Positive for Magnesium	PASSED TEST
Solution S	To Pass Test	PASSED TEST
Appearance of Solution	To Pass Test	PASSED TEST
Soluble Substances	2.00% max	0.37
Substances Insoluble in HAC	0.100% max	0.016
Chlorides as Cl	0.10% max	0.026
Sulphates as SO4	1.00% max	0.05
Calcium as Ca	1.50% max	0.04
Iron as Fe	0.07% max	0.002
Loss on Ignition	29.7-32.5%	30.4
Loss on Drying	2.00% max	0.25
Lead as Pb *	0.5 ppm max	LE 0.5
Particle Size Dist. D50	8-15 mic	10
Particle Size Dist. D90	60 mic max	29
Bulk Density(untapped)	0.65 g/cc min	0.72
Tapped Density(1000 taps)	0.90 g/cc min	1.00
Mastersizer curve shape	monomodal	PASSED TEST
Production Date		22-APR-2023
Expiry Date		21-APR-2027

Current ICH Q3D tested according to risk management summary (RMS)

\* - Tested once a month

For Takeda Pharmaceuticals LLC (Russia) the product is produced in accordance with Normative document FS 000307-240517.

### Batch No. 308233060

Quantity 1 x 8,000.000 KG

#### Legend

GT-Greater than

GE-Greater than or equal to

LT-Less than

LE-Less than or equal to

LABORATORIES & INSPECTION DEPARTMENT -

Form:PER0050/V14

QUALITY LAB COORDINATOR

TATYANA KRUPKIN

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